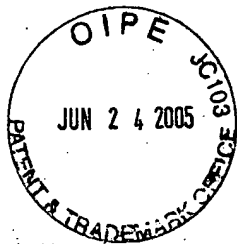


**COPY**



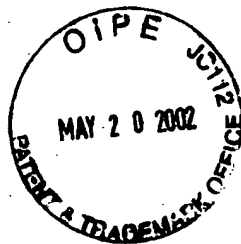
In re Application of: E. Sasha Paegle et al.  
Serial No.: 10/080,866  
Filed On: February 22, 2002  
Mailed On: May 15, 2002

Docket No.: P1732R1  
By: Janet E. Hasak  
Reg. No.: 28,616

✓  
5/21


The following has been received in the U.S. Patent Office on the date stamped:

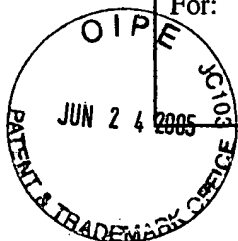
<u>x</u>	Information Disclosure Statement
<u>x</u>	Form 1449 with 81 References
<u>x</u>	Certificate of Mailing



**BEST AVAILABLE COPY**

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  E. Sasha Paegle et al.  Serial No.: 10/080,866	Group Art Unit: Unassigned  Examiner: Unassigned
Filed: February 22, 2002  For: PROCESS FOR PRODUCTION OF POLYPEPTIDES	<div style="text-align: center;"> <b>CERTIFICATE OF MAILING</b>  <small>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on</small>           May 15, 2002            Emily Dutra       </div>

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents  
 Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR

§1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-)" (nucleotide) and "BLAST Results B-1 - B-)" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☐ not given

☐ given for each listed item

☒ given for only non-English language listed item(s) [Required]

Item 16 of the PTO-1449 is provided in the form of an English language abstract. Item 55 is enclosed with an English language abstract.

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

Serial No.: 10/080,866  
Filed: February 22, 2002

Page 3

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,  
GENENTECH, INC.

Date: May 15, 2002

By: Janet E. Hasak  
Janet E. Hasak  
Reg. No. 28,616  
Telephone No. (650) 225-1896



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P1732R1Serial No.  
10/080866

## LIST OF DISCLOSURES CITED BY APPLICANT

Applicant  
Paegle et al.Filing Date  
22 Feb 2002

Group

JUN 24 2005 (Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	4,578,355	25.03.86				
	2	5,162,217	10.11.92				
	3	5,256,546	26.10.93				
	4	5,354,846	11.10.94				
	5	5,374,520	20.12.94				
	6	5,401,658	28.03.95				
	7	5,618,715	08.04.97				
	8	5,834,184	10.11.98				

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	9	131,843	23.01.85	EP			
	10	314,184	03.05.89	EP			
	11	467,676	22.01.92	EP			
	12	691,406	10.01.96	EP			
	13	700,997	13.03.96	EP			
	14	838,525	29.04.98	EP			
	15	893,502	27.01.99	EP			
	16	9,059,299	04.03.97	JP (ENGLISH ABSTRACT ONLY)			
	17	WO 85/02624	20.06.85	PCT			
	18	WO 85/04418	10.10.85	PCT			
	19	WO 88/06628	07.09.88	PCT			
	20	WO 89/03886	05.05.89	PCT			

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	21	Beck et al., "Efficient Production of Active Human Manganese Superoxide Dismutase in Escherichia coli." <u>Biotechnology</u> , 6:930-935 (Aug 1988)
	22	Bielawski et al., "Construction of a DNA-Polymerase I Overproducing Plasmid and Isolation of the Enzyme." <u>Acta Biochim. Pol.</u> 34(1):29-34 (1987)
	23	Borukhov and Goldfarb., "Purification and Assay of Escherichia coli Transcript Cleavage Factors GreA and GreB." <u>Meth. Enzymol.</u> 274:315-326 (1996)
	24	Borukhov et al., "GreA Protein: A Transcription Elongation Factor From Escherichia coli." <u>Proc. Natl. Acad. Sci. USA</u> 89:8899-8902 (Oct 1992)
	25	Borukhov et al., "Transcript Cleavage Factors from E. coli." <u>Cell</u> , 72:459-466 (Feb 1993)
	26	Chauhan and Apirion., "The Gene for a Small Stable RNA (10Sa RNA) of Escherichia coli." <u>Molecular Microbiology</u> , 3(11):1481-1485 (1989)
	27	Darst et al., "Crystallization of GreA, A Transcript Cleavage Factor From Escherichia coli." <u>J. Mol. Biol.</u> 242:582-585 (1994)

Examiner

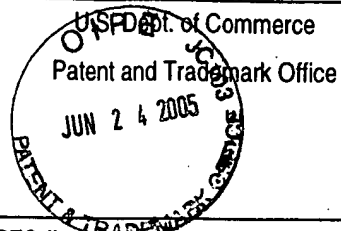
Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)



Atty Docket No.

P1732R1

Serial No.

10/080866

Applicant

Paegle et al.

Filing Date

22 Feb 2002

Group

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- |    |   |
|----|---|
| 28 | Das., "Transcription Antitermination by Lambda N Gene Product in a Well Defined Plasmid System." <u>Fed. Proc.</u> (72nd Annual Mtg. Amer. Soc. Bio. Chem. - Abstract 1291) 40(6):1764 (May 31-June 4 1981)   |
| 29 | Erie et al., "Multiple RNA Polymerase Conformations and GreA: Control of the Fidelity of Transcription." <u>Science</u> . 262:867-873 (1993)  |
| 30 | Feng et al., "GreA-Induced Transcript Cleavage in Transcription Complexes Containing Escherichia coli RNA Polymerase Is Controlled by Multiple Factors, Including Nascent Transcript Location and Structure." <u>J. Bio. Chem.</u> 269:22282-22294 (1994) |
| 31 | Feng et al., "Interactions Between RNA Polymerase and Transcript Affect GreA- And Gre-B-Mediated Reverse Translocation." <u>J. Cell. Biochem. Suppl.</u> (Abstract L408)18C:58 (1994)   |
| 32 | Franklin and Bennett., "The N Protein of Bacteriophage Lambda, Defined by its DNA Sequence, is Highly Basic." <u>Gene</u> . 8:107-119 (1979)  |
| 33 | Franklin., "N" Transcription Antitermination Proteins of Bacteriophages $\lambda$ , $\phi$ 21 and P22." <u>J. Mol. Bio.</u> 181:85-91 (1985)  |
| 34 | Franklin., "Clustered Arginine Residues of Bacteriophage $\lambda$ N Protein are Essential to Antitermination of Transcription, but Their Locale Cannot Compensate for boxB Loop Defects." <u>J. Mol. Bio.</u> 231:343-360 (1993)                         |
| 35 | Franklin., "Conservation of Genome Form but not Sequence in the Transcription Antitermination Determinants of Bacteriophages $\lambda$ , $\phi$ 21 and P22." <u>J. Mol. Bio.</u> 181:75-84 (1984)   |
| 36 | Friedman and Olson., "Evidence that a Nucleotide Sequence, "boxA," Is Involved in the Action of the NusA Protein." <u>Cell</u> . 34:143-149 (1983)  |
| 37 | Friedman et al., "Transcription-Dependent Competition for a Host Factor: The Function and Optimal Sequence of the Phage $\lambda$ boxA Transcription Antitermination Signal." <u>Genes Dev.</u> 4:2210-2222 (1990)  |
| 38 | Garcia et al., "The E. coli dnaY Gene Encodes an Arginine Transfer RNA." <u>Cell</u> . 45:453-459 (1986)  |
| 39 | Gatenby and Castleton., "Amplification of Maize Ribulose Bisphosphate Carboxylase Large Subunit Synthesis in E. coli by Transcriptional Fusion with the Lambda N Operon." <u>Mol. Gen. Genet.</u> 185:424-429 (1982)                                      |
| 40 | Greenblatt et al., "Transcriptional Antitermination." <u>Nature</u> . 364:401-406 (Jul 1993)  |
| 41 | Gu et al., "Nascent RNA Cleavage by Arrested RNA Polymerase II Does Not Require Upstream Translocation of the Elongation Complex on DNA." <u>J. Bio. Chem.</u> 268:25604-25616 (1993)   |
| 42 | Guo and Price., "Mechanism of DmS-II-Mediated Pause Suppression by Drosophila RNA Polymerase II." <u>J. Bio. Chem.</u> 268:18762-18770 (1993)   |
| 43 | Horiuchi et al., "Effects of pH on Expression and Stabilization of $\beta$ -Galactosidase by Recombinant E. coli with a Thermally-Inducible Expression System." <u>Biotechnology Lett.</u> 16:113-118 (1994)  |
| 44 | Hsu et al., "Escherichia coli Transcript Cleavage Factors GreA and GreB Stimulate Promoter Escape and Gene Expression In Vivo and In Vitro." <u>Proc. Natl. Acad. Sci. USA</u> 92:11588-11592 (1995)  |
| 45 | Hwang et al., "High Level Expression of Porcine Growth Hormone in Escherichia coli From an Expression Vector Containing Bacteriophage $\lambda$ PL and N Gene Untranslated Region." <u>Biochem. &amp; Biophys. Res. Comm.</u> 173:711-717 (1990)          |
| 46 | Izban and Luse., "Factor-Stimulated RNA Polymerase II Transcribes at Physiological Elongation Rates on Naked DNA but Very Poorly on Chromatin Templates." <u>J. Bio. Chem.</u> 267(19):13647-13655 (1992)   |
| 47 | Izban and Luse., "SII-Facilitated Transcript Cleavage in RNA Polymerase II Complexes Stalled Early After Initiation Occurs in Primarily Dinucleotide Increments." <u>J. Bio. Chem.</u> 268(17):12864-12873 (1993)   |

Examiner

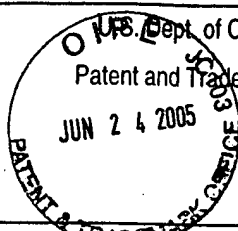
Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)



Atty Docket No.

P1732R1

Serial No.

10/080866

Applicant

Paegle et al.

Filing Date

22 Feb 2002

Group

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- |    |   |
|----|---|
| 48 | Izban and Luse., "The Increment of SII-Facilitated Transcript Cleavage Varies Dramatically Between Elongation Competent and Incompetent RNA Polymerase II Ternary Complexes." <u>J. Bio. Chem.</u> 268(17):12874-12885 (Jun 1993) |
| 49 | Izban and Luse., "The RNA Polymerase II Ternary Complex Cleaves the Nascent Transcript in a 3'→5' Direction in the Presence of Elongation Factor SII." <u>Genes &amp; Development</u> 6:1342-1356 (1992)                          |
| 50 | Kamasawa et al., "Optimization of β-Galactosidase Production by Recombinant E. coli with Thermo-Inducible Expression System." <u>IFAC Symp. Ser.</u> 10:255-258 (1992)  |
| 51 | Kassavetis and Gelduschek., "RNA Polymerase Marching Backward." <u>Science</u> . 259:944-945 (Feb 1993)   |
| 52 | Keller et al., "Role of a Peptide Tagging System in Degradation of Proteins Synthesized from Damaged Messenger RNA." <u>Science</u> . 271:990-993 (Feb 1996)  |
| 53 | Koullich et al., "Distinct Function on N and C-Terminal Domains of GreA, and Escherichia coli Transcript Cleavage Factor." <u>J. Mol. Bio.</u> 276:379-389 (1998)   |
| 54 | Koullich et al., "Domain Organization of Escherichia coli Transcript cleavage Factors GreA and GreB." <u>J. Bio. Chem.</u> 272(11):7201-7210 (Mar 1997)   |
| 55 | Kovgan et al., "Cloning and Expression of the HTLV-III Virus Surface Protein Gene in E. coli." <u>Vopr. Virusol.</u> (English Abstract Included) 31:485-489 (1986)  |
| 56 | Lazinski et al., "Sequence-Specific Recognition of RNA Hairpins by Bacteriophage Antiterminators Requires a Conserved Arginine-Rich Motif." <u>Cell</u> . 59:207-218 (Oct 1989)   |
| 57 | Lee et al., "GreA-Induced Transcript Cleavage Is Accompanied by Reverse Translocation to a Different Transcription Complex Conformation." <u>J. Bio. Chem.</u> 269(35):22295-22303 (1994)   |
| 58 | Li et al., "Antitermination of E. coli rRNA Transcription Is Caused by a Control Region Segment Containing Lambda nut-Like Sequences." <u>Cell</u> . 38:851-860 (Oct 1984)  |
| 59 | Lu et al., "Identification of greA Encoding a Transcriptional Elongation Factor as a Member of the carA-orf-carB-greA Operon in Pseudomonas aeruginosa PA01." <u>J. Bacteriology</u> . 179:3043-3046 (1997)                       |
| 60 | Makrides., "Strategies for Achieving High-Level Expression of Genes in Escherichia coli." <u>Microbiol. Rev.</u> 60(3):512-538 (1996)   |
| 61 | Marks and Wood., "Nucleotide Sequence of the Rickettsia prowazekii greA Homolog." <u>Nucleic Acids Research</u> . 20(14):3785 (1992)  |
| 62 | Martin-Gallardo et al., "Expression of the G Glycoprotein Gene of Human Respiratory Syncytial Virus in Salmonella Typhimurium." <u>J. Gen. Virol.</u> 74:453-458 (1993)   |
| 63 | Mertens et al., "Tight Transcriptional Control Mechanism Ensures Stable High-Level Expression from T7 Promoter-Based Expression Plasmids." <u>Biotechnology</u> . 13:175-179 (Feb 1995)   |
| 64 | Mogridge et al., "Involvement of boxA Nucleotides in the Formation of a Stable Ribonucleoprotein Complex Containing the Bacteriophage λ N Protein." <u>J. Bio. Chem.</u> 273(7):4143-4148 (1998)                                  |
| 65 | Mote and Reines., "Recognition of a Human Arrest Site Is Conserved Between RNA Polymerase II and Prokaryotic RNA Polymerases." <u>J. Bio. Chem.</u> 273(27):16843-16852 (1998)  |
| 66 | Olson et al., "Analysis of nutR: A Region of Phage Lambda Required for Antitermination of Transcription." <u>Cell</u> . 31:61-70 (Nov 1982)   |
| 67 | Orlova et al., "Intrinsic Transcript Cleavage Activity of RNA Polymerase." <u>Proc. Natl. Acad. Sci. USA</u> 92:4596-4600 (May 1995)  |

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

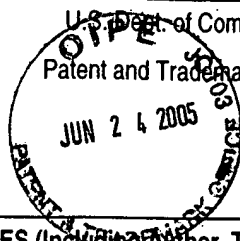
P1732R1

Serial No.

10/080866

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)



Applicant

Paegle et al.

Filing Date

22 Feb 2002

Group

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- |    |  |
|----|--|
| 68 | Patterson et al., "Bacteriophage Lambda N-Dependent Transcription Antitermination: Competition for an RNA Site May Regulate Antitermination." <u>J. Mol. Bio.</u> 236:217-228 (1994)                                     |
| 69 | Polyakov et al., "Visualization of the Binding Site for the Transcript Cleavage Factor GreB on Escherichia coli RNA Polymerase." <u>J. Mol. Bio.</u> 281:465-473 (1998)  |
| 70 | Rees et al., "Bacteriophage $\lambda$ N Protein Alone Can Induce Transcription Antitermination In Vitro." <u>Proc. Natl. Acad. Sci. USA</u> 93:342-346 (Jan 1996)  |
| 71 | Reines et al., "Transcription Elongation Factor SII (TFIIS) Enables RNA Polymerase II to Elongate Through a Block to Transcription in a Human Gene In Vitro." <u>J. Bio. Chem.</u> 264(18):10799-10809 (Jun 1989)        |
| 72 | Reines., "Elongation Factor-Dependent Transcript Shortening by Template-Engaged RNA Polymerase II." <u>J. Bio. Chem.</u> 267(6):3795-3800 (Feb 1992)   |
| 73 | Schauer et al., " $\lambda$ N Antitermination System: Functional Analysis of Phage Interactions with the Host NusA Protein." <u>J. Mol. Bio.</u> 194:679-690 (1987)  |
| 74 | Sluder et al., "Properties of a Drosophila RNA Polymerase II Elongation Factor." <u>J. Bio. Chem.</u> 264(15):8963-8969 (May 1989)   |
| 75 | Stanssens et al., "Inefficient Translation Initiation Causes Premature Transcription Termination in the lacZ Gene." <u>Cell</u> 44:711-718 (Mar 1986)  |
| 76 | Stebbins et al., "Crystal Structure of the GreA Transcript Cleavage Factor From Escherichia coli." <u>Nature</u> 373(16):636-640 (Feb 1995)  |
| 77 | Surratt et al., "Spontaneous Cleavage of RNA in Ternary Complexes of Escherichia coli RNA Polymerase and its Significance for the Mechanism of Transcription." <u>Proc. Natl. Acad. Sci. USA</u> 88:7983-7987 (Sep 1991) |
| 78 | Tu et al., "C-Terminal Extension of Truncated Recombinant Proteins in Escherichia coli with a 10Sa RNA Decapeptide." <u>J. Bio. Chem.</u> 270(16):9322-9326 (Apr 1995)   |
| 79 | Wang and Hawley., "Identification of a 3' -> 5' Exonuclease Activity Associated with Human RNA Polymerase II." <u>Proc. Natl. Acad. Sci. USA</u> 90:843-847 (Feb 1993)   |
| 80 | Weisberg and Gottesman., "Processive Antitermination." <u>J. Bacteriol.</u> 181(2):359-367 (Jan 1999)  |
| 81 | Zhukovskaya et al., "Inactive O <sup>6</sup> -Methylguanine-DNA Methyltransferase in Human Cells." <u>Nucleic Acids Research</u> 20(22):6081-6090 (1992)   |

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

E. Sasha Paegle et al.

Serial No.: 10/080,866

Filed: February 22, 2002

For: PROCESS FOR PRODUCTION OF  
POLYPEPTIDES

Group Art Unit: 1636

Examiner: Riggins, Patrick S.

Confirmation No: 9791

CUSTOMER NO: 09157

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

June 22, 2005

*Pamela Gavette*

Pamela Gavette

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR § 1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR § 1.114.

☒ **37 CFR § 1.97(c)**

- by the applicant after the period specified in 37 CFR § 1.97(b), but prior to the mailing date of any of a final action under 37 CFR § 1.113, or a notice of

06/27/2005 MWOLDGE1 00000004 070630 10080866

01 FC:1806 180.00 DA

allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.

☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449.

A copy of the items listed on the PTO-1449 form are supplied herewith, except for those patent(s), publication(s) or other information which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because **a)** ☐ they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120 **and/ or** because **b)** ☐ copies of United States patents and United States patent application publications are not required unless requested by the Office. 37 CFR §1.98(a)(2)(ii). See Final Rule **1287 OG** (October 12, 2004). Applicants stand ready to provide copies at the request of the Examiner.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: June 22 2005

By: Janet E. Hasak  
Janet E. Hasak  
Reg. No. 28,616  
Telephone No. (650) 225-1896

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1732R1

Serial No.

10/080,866

Applicant

Paegle et al.

Filing Date

22 Feb 2002

Group

1645

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

JUN 24 2005

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

Condon, Ciaran, et al., "Control of rRNA Transcription in Escherichia coli" Microbiological Reviews 59(4):623-645 (Dec 1995)

86

McKenney, K., et al., "A System to Study Promoter and Terminator Signals Recognized by Escherichia Coli RNA Polymerase" Gene Amplification and Analysis, Jack G. Chirikjian and Takis S. Papas 1981 Vol. 2:383-415 (1981)

87

Podhajska, A. J., et al., "Control of cloned gene expression by promoter inversion in vivo: construction of the heat-pulse-activated att-nutL-p-att-N module" Gene 40:163-168 (1985)

88

Richardson and Greenblatt, "Control of RNA chain elongation and termination" Escherichia coli and Salmonella: cellular and molecular biology, Washington, DC:ASM Press Vol. 1:822-848 (1996)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.